



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

RECEIVED MAR 23 1992

March 23, 1992

Mark Green, Commissioner  
New York City Department  
of Consumer Affairs  
42 Broadway  
New York, New York 10004

Dear Commissioner Green:

I am responding to your February 11, 1992, letter to Commissioner Kessler requesting that FDA act quickly to seize and then ban all hydroquinone-containing skin bleaching creams marketed over-the-counter (OTC) in the United States. Your letter specifically mentions a study from the National Toxicology Program (NTP) which suggests that hydroquinone could be carcinogenic.

We are aware of new information, including the NTP study, that raises questions concerning the safety of hydroquinone as an OTC skin bleaching product and are in the process of evaluating the data to decide what actions are appropriate. Besides the NTP technical report on the toxicology and carcinogenesis studies of hydroquinone, our scientists are currently reviewing the link between hydroquinone (1.5 to 2%) and exogenous ochronosis, as well as my other data on the safety of hydroquinone as an OTC skin bleaching drug product.

As part of this process, our Center for Drug Evaluation and Research has scheduled an April 8, 1992, meeting with the Nonprescription Drug Manufacturers Association's Hydroquinone Task Group at 3:00 p.m. in room 14B-45 of the Parklawn Building, to discuss the NTP study and the Task Group's research activities concerning the safety of hydroquinone (see enclosed letters). The meeting is open to any interested party, and representatives of your department are welcome to attend to listen to the discussion.

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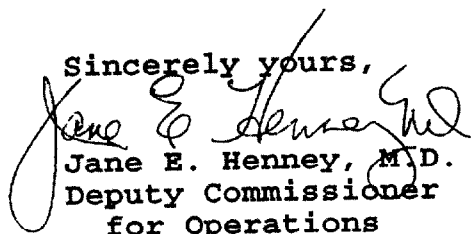
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Our final decision on the hydroquinone skin bleaching products is pending completion of our review of the data.

Thank you for writing and sharing your comments and concerns.

Sincerely yours,



Jane E. Henney, M.D.  
Deputy Commissioner  
for Operations

Enclosures